



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-0997; Docket No. CDC-2019-0087]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Standardized National Hypothesis Generating Questionnaire. The information collected will be used to define a core set of data elements to be used for hypothesis generation once a given situation is determined to be a multistate foodborne outbreak investigation.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0087 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Standardized National Hypothesis Generating Questionnaire (OMB Control No. 0920-0997, Exp. 2/29/2020) - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It is estimated that each year roughly one in six Americans get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. CDC and partners ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks, to limit the number of illnesses, and to learn how to prevent similar outbreaks from happening in the future.

Conducting interviews during the initial hypothesis-generating phase of multistate foodborne disease outbreaks presents numerous challenges. In the U.S. there is not a standard, national form or data collection system for illnesses caused by many enteric pathogens. Data elements for hypothesis generation must be developed and agreed upon for each investigation. This process can take several days to weeks and may cause interviews to occur long after a person becomes ill.

CDC requests a revision to this project to collect standardized information, called the Standardized National Hypothesis-Generating Questionnaire (SNHGQ), from individuals who have become ill during a multistate foodborne disease event. Since the questionnaire is designed to be administered by public health officials as part of multistate hypothesis-generating interview activities, this questionnaire is not expected to entail significant burden to respondents.

The Standardized National Hypothesis-Generating Core Elements Project was established with the goal to define a core set of data elements to be used for hypothesis generation during multistate foodborne investigations. These elements represent the minimum set of information that should be available for all outbreak-associated cases identified during hypothesis generation. The core elements would ensure that similar exposures would be ascertained across many jurisdictions, allowing for rapid pooling of data to improve the timeliness of hypothesis-generating analyses and shorten the time to pinpoint how and where contamination events occur.

The Standardized National Hypothesis Generating Questionnaire was designed as a data collection tool for the core elements, to be used when a multistate cluster of enteric disease infections is identified. The questionnaire is designed to be administered over the phone by public health officials to

collect core elements data from case-patients or their proxies. Both the content of the questionnaire (the core elements) and the format were developed through a series of working groups comprised of local, state, and federal public health partners.

Since the last revision of the SNHGQ in 2016, ORPB has investigated over 700 multistate foodborne and enteric clusters of infection involving over 26,000 ill people. Of which, an outbreak vehicle has been identified in 200 of these investigations. These outbreaks have led to over 50 recalls and countless regulatory actions that have removed millions of pounds of contaminated vehicles out of commerce. In almost all instances, the SNHGQ or iterations of the SNHGQ have been instrumental in the successful investigation of these outbreaks. The questionnaire has allowed investigators to more efficiently and effectively interview ill persons as they are identified. Because these exposures are captured in a common, standard format, we have been able to share and analyze data rapidly across jurisdictional lines. Faster interview response and analysis times have allowed for more rapid epidemiologic investigation and quicker regulatory action, thus helping to prevent thousands of additional illnesses from occurring and spurring industry to adopt and implement new food safety measures in an effort to prevent future outbreaks.

The total estimated annualized burden for the Standardized National Generating Questionnaire is 3,000 hours (approximately 4,000 individuals identified during the hypothesis-generating phase of outbreak investigations with 45 minutes/response). There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
All individuals identified as part of an outbreak investigation	Standardized National Hypothesis Generating Questionnaire	4,000	1	45/60	3,000
Total					3,000

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

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Centers for Disease Control and Prevention.

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